



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/830,033 | 10/22/2001 | Patrick C. Kung | 044574-5040 | 9303 |

9629 7590 06/07/2005

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,033

Applicant(s)

KUNG ET AL.

Examiner

Cheyne D. Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83, 84 and 87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83, 84 and 87 is/are rejected.
- 7) ☒ Claim(s) 83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

51000

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 16, 2005 has been entered.
2. Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
3. The Declaration Under 37 C.F.R. 1.132 executed by Dan Theodorescu has been fully considered. The 35 U.S.C. 103(a) rejection in view of Khwaja et al. and Schena et al. has been withdrawn. Further, it is noted that the Declaration Under 37 C.F.R. 1.132 has been fully considered as directed to the newly applied 35 U.S.C. 102(e)(2) rejection as being clearly anticipated by Khwaja et al. (US006113907A). The Declaration does not prevent said rejection because page 18 of the instant specification, Applicant has defined "an HBR Array constitutes a data set of two or more observations or measurements associated with an herbal composition." Khwaja et al. discloses, in Figures 4-6, a data set of two or more observations or measurements associated with the biological activities of the compounds

Art Unit: 1631

from St. John's Wort (column 40, section 6.3.7) which has been reasonably construed as the claimed HBR Array.

4. Claims 83, 84, and 87 are examined on the merits.

OBJECTION

5. Claim 83 is objected to because said claim contains improper internal periods. For example, the recitation of "a." or "i." is improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 84 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER.
8. Claim 84 has been amended to recite the limitation of "from one or more of the group..." which has been considered to be new matter. It is noted that the pointed to support (page 16, line 5) discloses "a biosystem comprising one or more different types..." which is different from the amended limitation. It is noted that the new limitation encompasses the selection of

Art Unit: 1631

“different cells” as well as “the same”, wherein the selection of the “the same” has not been found in the instant specification, as originally filed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in:

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 83, 84, and 87 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Khwaja et al. (US006113907A).
11. On page 18 of the instant specification, Applicant has defined “an HBR Array constitutes a data set of two or more observations or measurements associated with an herbal composition.” Khwaja et al. discloses, in Figures 4-6, a data set of two or more observations or measurements associated with the biological activities of the compounds from St. John’s Wort (column 40, section 6.3.7) which has been reasonably construed as the claimed HBR Array.

Art Unit: 1631

12. Khwaja et al. discloses a method for manufacturing pharmaceutical compositions from plant extracts wherein quality control is performed via standardization and control to provide reproducible material in the predictable and consistent treatment of patients (column 2, lines 39-51). The method of Khwaja et al. is useful in providing botanical materials which are sufficiently characterized and whose compositions are consistent between batches (column 12, lines 54-58). The method of Khwaja et al. comprises harvesting botanical material (whole or part), determining standardized bioactivity profile using, comparing the calculated bioactivity of the botanical composition to a bioactivity fingerprint standard, and determine whether the botanical material is a pharmaceutical grade St. John's Wort (column 9, line 50 to column 10, line 7). The type of markers includes the amount of the expression of viral reverse transcriptase (column 26, lines 19-34), inhibition of serotonin receptor expression (column 6, lines 52-53), and reduction of IL-6 expression (column 7, lines 3-5) (gene expression for markers). The method of Khwaja et al. is directed comparing fingerprint profile of the test compound to that of an established standard. If the test compound meets the established standards, then it is approved for pharmaceutical grade (column 17, lines 56-62). The standard bioactivity is determined by a similarity value (claim 2). Figures 4-6 illustrates (stored) a data set of two or more observations or measurements associated with the biological activities of the compounds from St. John's Wort (column 40, section 6.3.7) which has been reasonably construed as the claimed HBR Array, as in instant claim 83.
13. The method of Khwaja et al. has been demonstrated with rat forebrain membranes (column 33, lines 59-67), as in instant claim 84.

Art Unit: 1631

14. The method of Khwaja et al. comprising each active component has a standardized bioactivity profile (normalized) and measuring the amount of each of the active component(s) present in each of the marker fractions. The method further comprises calculating the bioactivity of each of the marker fractions based on the amount of each active component present and the standardized component bioactivity profile to provide a calculated bioactivity fingerprint of the aliquot; and comparing the calculated bioactivity fingerprint of the aliquot to a bioactivity fingerprint standard which has been established for a pharmaceutical grade St. John's Wort to provide a bioactivity fingerprint comparison to determine whether the botanical material is a pharmaceutical grade St. John's Wort is obtained based on the bioactivity fingerprint comparison. (column 9, lines 37-49), as in instant claim 87.

CONCLUSION

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.
16. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also

Art Unit: 1631

check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet.

The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

17. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly / *CDL*
5/30/05

Ardin H. Marschel 6/5/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER